MEMO ENDORSED

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September 28, 2023

Via ECF
Hon. Valerie E. Caproni, U.S.D.J.
United States District Court, Southern District of New York
40 Foley Square
New York, NY 10007

Re: *Kwasnik v. Oxford Health Insurance, Inc., et al.* Civil Action No. 1:22-cv-04767-VEC
Dear Judge Caproni:

In response to Oxford Healthcare, Inc.'s ("Oxford") letter dated September 27, 2023 regarding New York Department of Financial Service's ("DFS") guidelines, I am attaching two additional documents to be included in the Administrative Record: 1) DFS Insurance Circular Letter No. 3 (2021) published February 23, 2021 ("Circular No. 3") providing guidance on N.Y. Insurance Law §§ 3221(k)(6) and 4303(s) (the "IVF Mandate"); and 2) the 2021 online DFS "IVF and Fertility Preservation Law Q&A Guidance" published on August 10, 2021 (the "2021 Guidelines").

First, please note that Oxford did not provide Circular No. 3(Exhibit A) which was attached as an inoperable PDF link on OXFORD 000443. This circular, issued on February 23, 2021, provided guidance to authorized insurers, such as Oxford, to assist in the interpretation of the IVF Mandate.

Second, on August 10, 2021 the DFS issued the 2021 Guidelines (Exhibit B) after the issuance of Circular No. 3.

Oxford acknowledges that Plaintiff sought IVF services in 2021. Further, it appears that Oxford is acknowledging that it utilized outdated guidelines from 2019 through the course of Plaintiff's appeal's process which occurred in 2021. The guidelines that Plaintiff provided on September 18, 2023 are the same as the 2021 guidelines.

We ask the Courts permission to Bate's Stamp all 2021 documents that must be included in a complete administrative record.

Respectfully submitted,
Richard Kwasnik
Richard Kwasnik, Esq.

cc: Michael H. Bernstein, Esq. (via ECF)

Department of Financial Services

Insurance Circular Letter No. 3 (2021)

February 23, 2021

TO:	**All Insurers Authorized to Write Accident and Health Insurance in New York State, Article 43 Corporations, Health Maintenance Organizations, Student Health Plans Certified Pursuant to Insurance Law § 1124, Municipal Cooperative Health Benefit Plans, and Prepaid Health Services**
RE:	**Health Insurance Coverage of Infertility Treatments Regardless of Sexual Orientation or Gender Identity**

STATUTORY REFERENCES: N.Y. Insurance Law §§ 3216(l), 3221(h), 3221(k)(6), 4303(s), 4303(ll), and 4304(l)

I. Purpose

The purpose of this circular letter is to withdraw Insurance Circular Letter No. 7 (2017) and direct insurers authorized to write accident and health insurance in New York State, Article 43 corporations, health maintenance organizations, student health plans certified pursuant to Insurance Law § 1124, municipal cooperative health benefit plans, and prepaid health services plans that issue coverage subject to Insurance Law §§ 3221(k)(6) and 4303(s) (collectively, "issuers") to provide immediate coverage of diagnostic and treatment services, including prescription drugs, for the diagnosis and treatment of infertility ("basic infertility treatments") for individuals who are unable to conceive due to their sexual orientation or gender identity and are covered under individual, small group, and large group health insurance policies and contracts.

II. Discussion

Insurance Law §§ 3221(k)(6) and 4303(s) require a policy or contract that provides coverage for hospital care or surgical and medical care to provide coverage for diagnostic and treatment procedures used in the diagnosis and treatment of infertility. These sections of the Insurance Law further require a policy or contract that provides coverage for prescription drugs to cover prescription drugs approved by the federal Food and Drug Administration for use in the diagnosis and treatment of infertility. In addition, diagnostic and treatment procedures used in the diagnosis and treatment of infertility and prescription drugs are covered under comprehensive individual and small group health insurance policies and contracts as part of New York's essential health benefits package as described in Insurance Law §§ 3216(l), 3221(h), 4303(ll), and 4304(l).

In 2017, the Department of Financial Services ("Department") issued Circular Letter No. 7, which provided guidance to issuers based on the definition of "infertility" in effect at that time. In 2017, Insurance Law §§ 3221(k)(6)(C)(vi) and 4303(s)(3)(F) required issuers to make the determination of infertility in accordance with the standards and guidelines established and adopted by the American College of Obstetricians and Gynecologists and American Society for Reproductive Medicine ("ASRM"). The ASRM description of infertility provided that "[i]nfertility is a disease, defined by the failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination. Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after 6 months for women over age 35 years."

However, in 2019, Part L of Chapter 57 ("Part L") added Insurance Law §§ 3221(k)(6)(C)(v)(I) and 4303(s)(3)(E)(i) to amend the definition of "infertility" that was set forth in former Insurance Law §§ 3221(k)(6)(C)(vi)(I) and 4303(s)(3)(F)(i) to mean "a disease or condition characterized by the incapacity to impregnate another person or to conceive, defined by the failure to establish a clinical pregnancy after twelve months of regular, unprotected sexual intercourse or therapeutic donor insemination, or after six months of regular, unprotected sexual intercourse or therapeutic donor insemination for a female thirty-five years of age or older. Earlier evaluation and treatment may be warranted based on an individual's medical history or physical findings."

Part L also added new Insurance Law §§ 3221(k)(6)(C)(viii) and 4303(s)(3)(H) to prohibit an issuer providing coverage for infertility treatments from discriminating based on an individual's expected length of life, present or predicted disability, degree of medical dependency, perceived quality of life, or other health conditions, or based on personal characteristics, including age, sex, sexual orientation, marital status, or gender identity. Part L further added a new Insurance Law §§ 3221(k)(6)(C)(vii) and 4303(s)(3)(G) to require large group policies that provide medical, major medical or similar comprehensive-type coverage to cover three cycles of in-vitro fertilization ("IVF") when used in the treatment of infertility. The amendments made by Part L took effect on January 1, 2020 and applied to insurance policies and contracts issued, renewed, modified, altered, or amended on or after January 1, 2020.

Under the Insurance Law, an issuer must provide coverage regardless of sexual orientation, marital status, or gender identity. In addition, since the definition of infertility expressly contemplates coverage for infertility treatment earlier than 12 months, issuers should be mindful that, with respect to some individuals, earlier evaluation and treatment may be justified. It has come to the Department's attention that some issuers may be requiring some individuals to incur costs, due to their sexual orientation or gender identity, that heterosexual individuals do not incur in order to meet the definition of infertility. In particular, some issuers have denied coverage of basic infertility treatments, such as intrauterine insemination procedures, for some individuals who are unable to conceive without such treatment due to their sexual orientation or gender identity. These individuals may incur the high costs of basic infertility treatments for up to 12 months to demonstrate infertility in order to qualify for insurance coverage due to their sexual orientation or gender identity. This results in unfair discrimination for individuals due to their sexual orientation or gender identity, which is prohibited by Insurance Law §§ 3221(k)(6)(C)(viii) and 4303(s)(3)(H). Therefore, issuers must provide immediate coverage for basic infertility treatments (e.g., intrauterine insemination procedures) that are provided to individuals covered under an insurance policy or contract who are unable to conceive due to their sexual orientation or gender identity in order to prevent discrimination. Issuers that cover IVF procedures may consider whether basic infertility treatments, such as intrauterine insemination procedures, would be medically appropriate for the individual to attempt prior to covering IVF. This circular letter does not address surrogacy arrangements or require coverage for services that are not otherwise mandated to be covered under the Insurance Law.

III. Conclusion

Issuers are directed to provide immediate health insurance coverage for basic infertility treatments that are provided to individuals covered under an insurance policy or contract who are unable to conceive due to their sexual orientation or gender identity in accordance with the Insurance Law. In addition, Circular Letter No. 7 (2017) is withdrawn.

Please direct any questions regarding this circular letter by email to health@dfs.ny.gov.

Very truly yours,

Lisette Johnson
Chief, Health Bureau

Department of Financial Services

Health Insurers

Preservation Law Q&A Guidance

Part L of Chapter 57 of the Laws of 2019 included several changes to the Insurance Law provisions related to health insurance coverage for in-vitro fertilization (IVF) and fertility preservation services.

IVF - Applicability

Q-1. When does the IVF law go into effect?

The IVF law is effective January 1, 2020 and applies to policies and contracts issued or renewed in New York on or after that date.

Q-2. Which insurance policies and contracts are subject to this law?

New York Insurance Law §§ 3221(k)(6)(C) and 4303(s)(3) require large group insurance policies and contracts that provide medical, major medical, or similar comprehensive-type coverage and are delivered or issued for delivery in New York to cover three cycles of IVF used in the treatment of infertility. Large group means a group of more than 100 employees.

Q-3. Does the IVF law apply to grandfathered health plans?

Yes. The IVF law applies to grandfathered health plans.

Q-4. Does the IVF law apply to self-funded ERISA plans?

No. The IVF law does not apply to self-funded ERISA plans.

IVF - Covered Services

Q-5. Are there any prerequisites or conditions for approval of IVF coverage?

An insured seeking IVF must be diagnosed with infertility, which is defined as a disease or condition characterized by the incapacity to impregnate another person or to conceive, due to the failure to establish a clinical pregnancy after 12 months of regular, unprotected sexual intercourse or therapeutic donor insemination, or after six months of regular unprotected sexual intercourse or therapeutic donor insemination for a female 35 years of age or older. Earlier evaluation and treatment may be warranted based on an individual's medical history or physical findings.

Q-6. What IVF services are required to be covered?

The law requires coverage for three cycles of IVF, including all treatment that starts when preparatory medications are administered for ovarian stimulation for oocyte retrieval with the intent of undergoing IVF using a fresh embryo transfer or medications are administered for endometrial preparation with the intent of undergoing IVF using a frozen embryo transfer.

Q-7. Does the IVF law require coverage of prescription drugs prescribed in connection with IVF services if the large group health plan does not otherwise include a prescription drug benefit?

Yes. Medications, including prescription drugs, are covered under the IVF benefit. New York Insurance Law §§ 3221(k)(6)(C)(vii) and 4303(s)(3)(G) define an IVF "cycle" as all treatment that starts when preparatory medications are administered for ovarian stimulation for oocyte retrieval with the intent of undergoing IVF using a fresh embryo transfer or medications are administered for endometrial preparation with the intent of undergoing IVF using a frozen embryo transfer.

Q-8. Is freezing and/or storage of oocytes or embryos covered as part of IVF services?

Yes. Issuers must cover oocyte and/or embryo storage in connection with an intended in-vitro fertilization procedure if medically necessary until the three required IVF cycles are provided.

Q-9. Does oocyte retrieval with the intent of freezing embryos and the planned and impending first implantation of the frozen embryo(s) resulting from the retrieved oocytes count as one IVF cycle or two IVF cycles?

The retrieval of oocytes, creating and freezing of embryos, and the planned and impending first implantation of those frozen embryo(s) when part of an insured's IVF treatment plan counts as one cycle toward the three-cycle limit on IVF coverage.

Q-10. Does a frozen embryo transfer cycle done without oocyte retrieval count towards the three-cycle limit on IVF coverage?

Yes. The law defines "cycle" to mean all treatment that starts when preparatory medications are administered for ovarian stimulation for oocyte retrieval with the intent of undergoing IVF using a fresh embryo transfer or medications are administered for endometrial preparation with the intent of undergoing IVF using a frozen embryo transfer.

Q-11. Does oocyte retrieval under the fertility preservation benefit count as an IVF cycle?

No. Fertility preservation services are a separate benefit to preserve fertility when a medical treatment will directly or indirectly result in iatrogenic infertility and do not count towards the three-cycle limit on IVF benefits.

IVF - Cost-Sharing & Limitations

Q-12. May IVF services be subject to deductibles, copayments, or coinsurance?

Yes. Cost-sharing such as deductibles, copayments, and coinsurance may be imposed on IVF services as long as the cost-sharing is consistent with other benefits in the policy or contract.

Q-13. Does the law permit annual dollar limitations on IVF coverage?

No. Issuers may not impose annual dollar limits on IVF services.

Q-14. Does the law permit lifetime limitations on IVF coverage?

Yes. Issuers may limit coverage to three cycles of IVF over the life of the insured. Issuers may not count cycles paid for by the insured out-of-pocket or cycles covered by other issuers towards the three-cycle limit. However, a cycle covered by the issuer that began, but was not completed, counts towards the three-cycle limit.

Q-15. Are age restrictions permitted for IVF coverage?

No. Age restrictions are not permitted for IVF coverage. In addition, age restrictions are no longer permitted for any other covered infertility services.

Q-16. Are issuers required to cover IVF treatment for persons who have undergone voluntary sterilization procedures?

No. Issuers are not required to cover procedures to reverse a previous voluntary sterilization procedure or infertility treatment for a person in connection with such reversal.

Q-17. Will IVF treatments completed prior to January 1, 2020 count toward the three-cycle per lifetime limit?

No. Any treatments completed prior to January 1, 2020 will not count toward the IVF law's three-cycle per lifetime limit.

Q-18. May an issuer limit coverage of IVF to in-network providers?

If an issuer only provides coverage for in-network benefits (e.g., an EPO or HMO) in a policy or contract, coverage may be limited to in-network providers for IVF unless the issuer does not have an in-network provider with the appropriate training and expertise to meet the needs of the insured. If the policy or contract provides coverage for out-of-network services (e.g., a PPO or POS), coverage for out-of-network IVF services must also be provided.

IVF - Medical Necessity & Drug Formularies

Q-19. Does the law permit preauthorization for IVF coverage?

Yes. Issuers may require preauthorization for IVF services.

Q-20. Does the law permit IVF services to be reviewed for medical necessity?

Yes. However, issuers are prohibited from discriminating based on an insured's expected length of life, present or predicted disability, degree of medical dependency, perceived quality of life or other health conditions, or personal characteristics, including age, sex, sexual orientation, marital status, or gender identity.

Q-21. May issuers impose formulary requirements on prescription drugs related to IVF?

Yes. IVF prescription drugs may be subject to the issuer's formulary requirements. However, any plan design that limits coverage to those prescription drugs on the issuer's formulary drug list must comply with the formulary exception process in 45 CFR § 156.122 and Insurance Law §§ 3242 and 4329, and any other laws or requirements applicable to prescription drug coverage (e.g., the prohibition on more than three tiers or requirements regarding retail pharmacies).

IVF - Coordination of Coverage

Q-22. Part of the IVF process includes collecting sperm. Should that service be covered as part of the member's IVF coverage, or should it be part of the spouse's or partner's coverage?

Collecting sperm is part of the IVF benefit. However, if the woman and her partner both have IVF coverage, the coverage for collection may be coordinated pursuant to coordination of benefits rules.

Q-23. If an insured uses their IVF benefit but did not exhaust the three-cycle limit when covered by Issuer A, has embryos that are being stored, and then switches insurance coverage from Issuer A to Issuer B, what are the responsibilities of Issuer A and Issuer B for coverage of the storage costs?

Once the insured's insurance policy or contract terminates, Issuer A would no longer be responsible for the storage costs. Issuer B would be required to provide coverage for the storage costs if the insured is determined to be eligible for IVF benefits under the insurance policy or contract with Issuer B.

Fertility Preservation Coverage - Applicability

Q-1. When does the fertility preservation law go into effect?

The fertility preservation law is effective January 1, 2020 and applies to policies and contracts issued or renewed in New York on or after that date.

Q-2. Which insurance policies and contracts are subject to this law?

New York Insurance Law §§ 3216(i)(13)(C), 3221(k)(6)(C), and 4303(s)(3) require individual, small, and large group insurance policies or contracts that provide hospital, surgical and medical, major medical, or comprehensive care and are delivered or issued for delivery in New York to cover fertility preservation services for people with iatrogenic infertility.

Q-3. Does the fertility preservation law apply to grandfathered health plans?

Yes. The fertility preservation law applies to grandfathered health plans.

Q-4. Does the fertility preservation law apply to self-funded ERISA plans?

No. The fertility preservation law does not apply to self-funded ERISA plans.

Fertility Preservation Coverage - Covered Services

Q-5. When are fertility preservation services required to be covered?

New York Insurance Law §§ 3216(i)(C)(I), 3221(k)(6)(C)(v)(II), and 4303(s)(3)(E)(ii) require coverage for standard fertility preservation services for individuals when a medical treatment will directly or indirectly result in "iatrogenic infertility," which is an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes.

Q-6. Are fertility preservation services covered for insureds who are about to undergo gender affirming care for the treatment of gender dysphoria?

Yes. If the medical treatment for gender dysphoria will directly or indirectly result in "iatrogenic infertility," which is an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes.

Q-7. What fertility preservation services are required to be covered?

Standard fertility preservation services are required to be covered. These services include the collecting, freezing, preserving, and storing of ova or sperm and other standard services that are not experimental or investigational.

Q-8. If an insured has a disease that may require treatment that causes iatrogenic infertility, how soon before the treatment would an issuer be required to cover fertility preservation services?

An issuer may review fertility preservation services for medical necessity. As such, an issuer may consider the treatment plan being recommended as part of that review.

Q-9. Does the fertility preservation law require coverage of prescription drugs prescribed in connection with fertility preservation services if the large group health plan does not otherwise include a prescription drug benefit?

Yes. The law requires coverage for standard fertility preservation services when medical treatment would directly or indirectly cause iatrogenic infertility. Standard fertility preservation services include using prescription drugs to collect ova.

Fertility Preservation Coverage - Cost-Sharing & Limitations

Q-10. May fertility preservation services be subject to deductibles, copayments, or coinsurance?

Yes. Cost-sharing such as deductibles, copayments, and coinsurance may be imposed on fertility preservation services as long as the cost-sharing is consistent with other benefits in the policy or contract.

Q-11. Does the law permit annual dollar limitations on fertility preservation services?

No. Issuers may not impose annual dollar limits on fertility preservation services.

Q-12. Does the law permit lifetime limitations on fertility preservation services?

No. Issuers may not impose lifetime limitations on fertility preservation services.

Q-13. Are age restrictions permitted for fertility preservation services?

No. Age restrictions are not permitted for fertility preservation services. In addition, age restrictions are no longer permitted for any other covered infertility services.

Q-14. May issuers limit the duration of the storage for the ova or sperm?

The fertility preservation law does not include a specific limit on the duration of storage for ova or sperm. However, issuers may review the services for medical necessity.

Q-15. Is IVF required as a fertility preservation service?

No. IVF is not required as a fertility preservation service.

Q-16. May an issuer limit coverage of fertility preservation services to in-network providers?

If an issuer only provides coverage for in-network benefits (e.g., an EPO or HMO) in a policy or contract, coverage may be limited to in-network providers for fertility preservation services unless the issuer does not have an in-network provider with the appropriate training and expertise to meet the needs of the insured. If the policy or contract provides coverage for out-of-network services (e.g., a PPO or POS), coverage for out-of-network fertility preservation services must also be provided.

Fertility Preservation Coverage - Medical Necessity & Drug Formularies

Q-17. Does the law permit preauthorization for fertility preservation services?

Yes. Issuers may require preauthorization for fertility preservation services.

Q-18. Does the law permit fertility preservation services to be reviewed for medical necessity?

Yes. However, issuers are prohibited from discriminating based on an insured's expected length of life, present or predicted disability, degree of medical dependency, perceived quality of life or other health conditions, or personal characteristics, including age, sex, sexual orientation, marital status, or gender identity.

Q-19. May issuers impose formulary requirements on prescription drugs related to fertility preservation services?

Yes. Prescription drugs for fertility preservation services may be subject to the issuer's formulary requirements. However, any plan design that limits coverage to those prescription drugs on the issuer's formulary drug list must comply with the formulary exception process in 45 CFR § 156.122 and Insurance Law §§ 3242 and 4329, and any other laws or requirements applicable to prescription drug coverage (e.g., the prohibition on more than three tiers or requirements regarding retail pharmacies).

Fertility Preservation - Coordination of Coverage

Q-20. If an insured uses their fertility preservation services benefit and has ova or sperm that is currently in storage when covered by Issuer A, and then switches insurance coverage from Issuer A to Issuer B, what are the responsibilities of Issuer A and Issuer B for the storage costs?

Once the insured's insurance policy or contract terminates, Issuer A would no longer be responsible for the storage costs. Issuer B would be required to provide coverage for the storage costs if the insured is determined to be eligible for fertility preservation benefits under the insurance policy or contract with Issuer B.

Insurance Industry Questions

If you are unable to find the answer to your insurance question here, check our FAQs. If you have a question or need assistance, call (800) 342-3736 (M-F, 8:30 AM to 4:30 PM). Local calls can be made to (212) 480-6400 or (518) 474-6600.

The Court construes Plaintiff's letter as a motion to supplement the administrative record with the documents attached herein as opposed to the documents attached to Plaintiff's September 19, 2023 letter, which included guidance documents from 2023. Defendant's deadline to respond to Plaintiff's motion is **October 3, 2023**.

SO ORDERED.

Date: 9/29/2023

HON. VALERIE CAPRONI
UNITED STATES DISTRICT JUDGE